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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,135 | 10/29/2002 | Teruo Oku | 210229USOPCT | 1330 |

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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,135

Applicant(s)

OKU ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005 and 29 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 8, 10 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 15 and 17 is/are allowed.
- 6) ☒ Claim(s) 8 and 10 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 7, 8, 10 and 15-17 are pending in the application.

Rejections made in the previous Office Action which do not appear below have been overcome by Applicants amendment to the claim(s) or cancellation of the claim(s). Therefore, arguments pertaining to these rejections will not be addressed.

Information Disclosure Statement

The copending applications listed on information disclosure statements filed June 30, 2004 and September 3, 2004 have been considered. However, since the copending applications were not properly listed on a Form 1449, these copending applications will not be printed on any patent resulting from the instant application.

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Rejections made in the previous Office Action that do not appear below have been overcome by the amendment to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claim 16 is objected to because of the following informalities: an "or" should be added after compound (62). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases/disorders such as

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diabetes, osteoporosis, hypertension, atherosclerosis, polycystic ovary syndrome, etc., does not reasonably provide enablement for the prophylaxis, or prevention, of all the diseases/disorders listed in claims 8 and 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and

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8. the level of the skill in the art.

In the instant case, Applicants are claiming a pharmaceutical preparation (claim 8) for the prophylaxis or treatment of a number of diseases (e.g., diabetes, diabetic complications, polycystic ovary syndrome, skin disorders, etc.). Applicants also are claiming (claim 10) a method of preventing or treating a number of the same diseases.

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

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The various diseases/disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. For example, Applicants claims embrace a method of preventing or treating diabetic complications. The instant specification does not give any guidance as to the full range of diabetic complicating diseases that could be treated or prevented using the instant claimed process. In order to practice the claimed invention, one skilled in the art would have to speculate which diabetic complicating diseases/disorders could be prevented using the compounds found in the instant claims. The number of possible diabetic complicating diseases/disorders embraced by the claims would impose undue experimentation on the skilled art worker. Applicants have not demonstrated that all of the diseases/disorders embraced by instant claims 8 and 10 could be prevented or treated. Therefore, based on the

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unpredictable nature of the invention, and the state of the prior art would prevent one skilled in the art from accepting any therapeutic regimen on its face.

Response to Arguments

Applicants' arguments filed January 21, 2005 and April 29, 2005 have been fully considered. Applicants argue that the diseases/disorders found in instant claims 8 and 10 are enabled. Applicants argue that the references provided teach that the list of diseases in instant claims 8 and 10 are treatable.

In response, Applicants' arguments and references have been considered. The submitted references teach that the diseases/disorders listed in instant claims 8 and 10 are treatable. However, nothing in the instant specification or the various references would lead one skilled in the art, based on the unpredictable nature of the invention, and the state of the prior art, that the instant claimed compounds and compositions would

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prevent (or prophylaxis) every disease/disorder listed in instant claims 8 and 10. The various diseases/disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Further, there is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the diseases/disorders claimed therein. Therefore, the claims as such lack enablement.

Allowable Subject Matter

Claims 7, 15 and 17 are allowed over the art of record.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action.

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Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

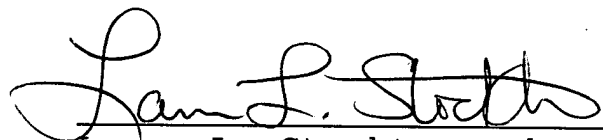
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

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(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

July 22, 2005